UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/758,173	01/12/2001	Darrell R. Anderson	PM 0276603 037003	1215

7590 05/27/2003

PILLSBURY WINTHROP L.L.P.
1600 TYSONS BOULEVARD
MCLEAN, VA 22102

EXAMINER	
GAMBEL, PHILLIP	

ART UNIT	PAPER NUMBER
1644	13

DATE MAILED: 05/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)
	09/758173	ANDERSON
	Examiner	Art Unit
	GAMBEL	1644

-- The MAILING DATE f this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 3/11/03

2a)☑ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☑ Claim(s) _____ is/are pending in the application. 21, 23-27

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☑ Claim(s) _____ is/are rejected. 21, 25, 27-31, 33-36

7)☑ Claim(s) _____ is/are objected to. 23, 26, 32, 37

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☑ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☑ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4)☐ Interview Summary (PTO-413) Paper No(s). _____.
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other:

DETAILED ACTION

1. Applicant's amendment, filed 3/11/03 (Paper No. 12), has been entered.
Claim 22 has been canceled. Claims 1-20 have been canceled previously.
Claims 21, 23,2 4, 32 and 33 have been amended.
Claim 37 has been added.

Claims 21 and 23-37 are pending and being acted upon as they read on the election invention of administering anti-B7.1 antibodies to treat B cell lymphoma.

2. The text of those sections of Title 35 USC not included in this Action can be found in a prior Action.
This Office Action will be in response to applicant's arguments, filed 3/11/03 (Paper No. 12).
The rejections of record can be found in the previous Office Action (Paper No. 10).

3. Again, applicant is reminded to amend the first line of the specification to update the status of the priority documents. For example, USSN 08/487,550 is now U.S. Patent No. 6,113,898.

4. Again, The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. Applicant should restrict the title to the claimed invention.

5. Again, the Abstract of the Disclosure is objected to because it does not adequately describe the claimed invention. Correction is required. See MPEP 608.01(b).

6. Upon reconsideration of applicant's submission of the attached in-house manuscript by Hariharan and Hanna showing that anti-B7-1 antibodies operate successfully in vivo to inhibit the growth of B lymphoma cells in a similar fashion to the unconjugated anti-CD20 rituximab, which inhibits B cell lymphoma, filed 3/11/03 (Paper No. 12); the previous rejection under 35 U.S.C. U.S.C. § 112, first paragraph, enablement with respect to methods of inhibiting B lymphoma cells with unconjugated anti-B7.1 antibodies has been withdrawn.

Also, see Kandasamy et al. Blood (11 Par 1): page 608a (2001).

7. Upon reconsideration of applicant's amended claims, filed 3/11/03 (Paper No. 12), the previous rejection under 35 U.S.C. § 112, second paragraph, has been withdrawn.

8. Claims 21, 25, 27-31, 33-36 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Imam et al. (U.S. Patent No. 5,304,635) in view of Delabie et al. (Blood 82: 2845-2852, 1993) AND/OR Munro et al. (Blood 83: 793-798, 1994), Falini et al. (Lancet 339: 1195-1196, 1992) and the well known generation of recombinant antibodies, including primatized antibodies and dosing known to the skilled artisan at the time the invention was made as acknowledged by pages 13-16 and 21-39 of the instant specification essentially for the reasons of record set forth in the previous Office Action (Paper No. 10).

Applicant's arguments, filed 3/11/03 (Paper No. 12), have been fully considered but are not found convincing essentially for the reasons of record.

In contrast to applicant's assertions of the rejection is based upon an "obvious-to-try" standard; it is by now well understood that the ultimate conclusion of law that claimed subject matter as a whole would have been obvious under 35 USC 103 may at times properly be drawn from an inference of fact arising from prior art teachings which could be considered an inference that it would be "obvious to try" that which is claimed. In re O'Farrell, 853 F.2d 894; 7 USPQ 2d 1973 (Fed. Cir. 1988); Contour Saws Inc. v. Starrett Co., 444 F. 2d 433, 170 USPQ 433 (Ct.App. 1977); In re Marzocchi, 439 F. 2d 220, 169 USPQ 367 (CCPA 1977); In re Lindell, 385 F. 2d 435, 155 USPQ 521 (CCPA 1967). The evidence of purported unobvious results of record in this application is insufficient to overcome the inference of fact in this case. Therefore the above claims remain rejected under 35 USC 103 for the reasons above and also those set forth in the previous Office Action, which are reiterated herein for applicant's convenience.

In contrast to applicant's assertions, there was sufficient motivation and expectation of success in the prior art to treat B cell lymphomas with anti-B7-1 antibodies, as set forth of record and reiterated herein for applicant's convenience.

Imam et al. teach the use of a growth inhibiting amount of a B-cell specific antibodies, including radioimmunotherapy, to treat B cell lymphoma's such as Hodgkin's lymphoma (see entire documents, including Background of the Invention, including column 3, lines 11-12 and column 4; Summary of the Invention, including column 5, lines 35-40; Detailed Description of the Invention, including columns 9-10, overlapping paragraph).

Imam et al. differs from the claimed methods by not disclosing the that the B cell antigen target of B cell lymphomas was B7-1.

Delabie et al. (Blood 82: 2845-2852, 1993) teach the B7/BB1 molecule (B7-1) was expressed on Reed-Sternberg cells in Hodgkin's Disease and contributes to the Hodgkin's syndrome (see entire document, including Abstract). Delabie et al. also teach that B7/BB1 was also expressed on subpopulations of neoplastic Cells of follicular lymphomas and anaplastic large-cell lymphoma (see Discussion, including page 2851, column 1). Delabie et al. also discuss that cell-mediated cytotoxic killing of Reed-Sternberg cells might explain the relative indolent clinical behavior of most subtypes of Hodgkin's disease (page 2851, column 1, paragraph 2).

Munro et al. (Blood 83: 793-798, 1994) teach the in vivo expression of B7 by benign transformed germinal center B cells and B cells of follicular lymphomas (see entire document, including the Abstract and Discussion). Also, Munro et al. teach that the majority of Reed-Sternberg cells or malignant mononuclear variants, which potentially contributes to the lymphocytic accumulation that is a feature of Hodgkin's disease (see entire document, including Abstract and Discussion).

Falini et al. teach the use of immunotoxin to treat Hodgkin's disease, providing an expectation of success in treating B cell lymphomas with antibodies that bind Hodgkin and Reed-Sternberg cells (see entire document, including Abstract). Falini et al. also note manipulating dosing and timing of administration to increase efficacy (see page 1196, column 2, paragraph 1). Further, Falini et al. note that the use of chimeric or humanized antibodies would circumvent the problems associated with repeated dosing (see page 1196, column 2, paragraph 1), thereby providing further motivation and expectation of success in applying the well known and practiced use of recombinant antibodies for human therapy.

In support, pages 13-16 and 21-39 of the instant specification acknowledge the well known generation of recombinant antibodies, including primatized antibodies and the antibodies comprising different human gamma chains constant regions for human therapy at the time the invention was made. Further, the specification also acknowledges the amount of an antibody useful to produce a therapeutic effect can be determined by standard techniques well known to those of ordinary skill in the art (e.g., see page 32, paragraph 2 and page 34, paragraph 2).

Given the experience by the ordinary artisan in the art at the time the invention was made, as taught by Falini et al. And acknowledged by the specification as filed, the claimed dosing and modes of administration would have been known and practiced by the ordinary artisan at the time the invention was made in achieving the therapeutic endpoint of treating B cell lymphomas.

Therefore, one of ordinary skill in the art would have been motivated to treat B cell lymphomas with B7-1-specific antibodies, particularly B7-1-specific antibodies conjugated to a cytotoxic agent, given the teachings of the prior art teachings that anti-B cell antibody conjugates treat B cell lymphomas and that anti-B7-1 antibodies bind B cell lymphomas at the time the invention was made. Further, the priori art provides motivation to treat B cell lymphomas by targeting Reed-Sternberg cells, which contribute to the clinical manifestations of Hodgkin's Disease.

From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Applicant's arguments are not found persuasive.

9. Claims 23, 26, 32 and 37 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 21, 25, 27-31, 33-36 are rejected under 35 U.S.C. § 103(a) for the reasons set forth above.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

PHILLIP GAMBEL

Phillip Gambel, PhD.
Primary Examiner
Technology Center 1600
May 23, 2003